

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listing, of all claims in the application:

Listing of Claims:

1. (Previously presented) A two-part prosthetic spinal nucleus device for replacing a nucleus of a spinal disc and being implanted in an intervertebral space within a natural annulus and between natural end plates attached to adjacent axially spaced upper and lower vertebral bones, the device comprising:

a rigid upper shell having a one-piece elongate body having a predetermined length between opposite narrow ends and a predetermined width between opposite elongate sides and including a smooth outer surface having a flat configuration extending substantially entirely across the length and width of the shell for facing and non-invasively contacting the natural end plate of the upper vertebra for sliding engagement therewith and sized to fit within the natural annulus of the spinal disc;

a rigid lower shell having a one-piece elongate body having a predetermined length between opposite narrow ends and a predetermined width between opposite elongate sides and including a smooth outer surface having a flat configuration extending substantially entirely across the length and width of the shell for facing and non-invasively contacting the natural end plate of the lower vertebra for sliding engagement therewith and sized to fit within the natural annulus of the spinal disc;

inner, arcuate bearing surfaces of the one-piece bodies of the upper and lower shells that are in sliding engagement with each other ~~each extending substantially entirely~~ including a dome-shaped inner bearing surface of one of the shell bodies having truncated, diametrically opposite edge portions that extend along the opposite elongate sides of the one shell body such that a diameter of the dome-shaped inner bearing surface is longer than the width of the one shell body and the dome-shaped inner bearing surface extends substantially across the entire

~~width of the one shell body between the opposite edge portions across the width of the respective shell bodies to the opposite sides thereof such that the inner, arcuate bearing surfaces have the widthwise size thereof maximized for distributing loading exerted by the adjacent vertebrae across substantially the entire width of the respective shell bodies; and~~

the elongate sides of each of the shell bodies extending lengthwise between the narrow ends thereof so that the sides are longer than the width across the narrow ends to allow the shells to be arranged with narrow ends of the shell bodies leading the shells as the shells are inserted through an incision smaller than the elongated sides of the shell bodies so that the natural annulus retains the shells in the intervertebral space with the smooth outer surfaces of the shell bodies extending continuously without interruption across the entire extent of the length and the width thereof between the ends and sides of the respective shell bodies.

2. (Canceled)

3. (Previously presented) The device of claim 1 wherein the shell bodies are configured to be sequentially inserted through the incision in the annulus, and be assembled within the annulus.

4.-20. (Canceled)

21. (Previously presented) The device of claim 1 wherein at least one of the shells includes a gripping projection integral with the body of the one shell configured to allow a separate tool to grip around the projection for tool insertion of the shells through the annulus incision into the intervertebral space and shifting of the shells therein so that the narrow shell ends are not aligned with an insertion direction of the shells through the incision.

22. (Previously presented) The device of claim 21 wherein the gripping projection comprises a gripping post of the at least one of the upper and lower shells that projects from the one shell toward the other of the upper and lower shells.

23. (Previously presented) The device of claim 21 wherein the gripping projection includes an arcuate engagement surface for rotating the one shell with the tool, and a generally flat abutment surface for locking the one shell against rotation with the tool.

24. (Previously presented) The device of claim 1 wherein the inner, arcuate bearing surfaces comprise engaging concave and convex bearing surfaces of the upper and lower shell bodies that bear against each other for substantially the entire arcuate extent thereof without discontinuities in the bearing surfaces.

25. (Previously presented) The device of claim 24 wherein the shell bodies include flat surface portions adjacent the concave and convex bearing surfaces.

26. (Previously presented) The device of claim 25 wherein the flat surface portion of one of the shell bodies includes an integral gripping post projecting away therefrom.

27. (Currently amended) The device of claim 1 wherein one of the shell bodies includes a flat surface portion and the inner bearing surface of the one shell body is a concave surface portion recessed from the flat surface portion, and the other shell body includes a flat surface portion and the inner bearing surface of the other shell body is [[a]] the dome-shaped inner bearing surface projecting beyond the flat surface portion of the other shell body.

28.-30. (Canceled)

31. (Previously presented) The device of claim 1 wherein the bodies of the rigid upper shell and the rigid lower shell are entirely of a polyetheretherketone (PEEK) material so that the PEEK inner bearing surfaces bear and articulate against each other and provide optimized wear resistance and cyclic load bearing capacity upon being implanted in the intervertebral space in the annulus.

32-41. (Canceled)

42. (Currently Amended) A nucleus implant device for replacing a nucleus of an intervertebral spinal disc leaving the natural spinal annulus and end plates of adjacent upper and lower vertebrae intact, the nucleus implant device comprising:

an upper load bearing member having a width between opposite sides thereof for being implanted in an intervertebral space within the intact, natural annulus adjacent the upper vertebra;

a lower load bearing member having a width between opposite sides thereof for being implanted in the intervertebral space within the intact, natural annulus adjacent the lower vertebra;

a polyetheretherketone (PEEK) material of both the upper load bearing member and the lower load bearing member so that the load bearing members are of matching material;

PEEK outer bearing surfaces of the matched PEEK load bearing members having a smooth, flat configuration for substantially the entire extent thereof so as to lack any protrusions projecting outwardly therefrom for non-invasive sliding engagement with the corresponding intact, natural end plates; and

PEEK inner bearing surfaces of the matched PEEK load bearing members each having an arcuate configuration ~~that extends substantially across the entire width of each of the bearing members~~ including a dome-shaped inner bearing surface of one of the PEEK load bearing members having truncated surface portions substantially coincident with the opposite sides of the one bearing member such that the truncated surface portions extend from the dome-shaped

inner bearing surface along the opposite sides of the one bearing member such that a diameter of the dome-shaped inner bearing surface is longer than the width of the one bearing member and the dome-shaped inner bearing surface extends substantially across the entire width of the one bearing member ~~to maximize the widthwise size of the dome~~, and a corresponding arcuate recess-shaped inner bearing surface of the other of the PEEK load bearing members configured to cooperate with the dome-shaped inner bearing surface and together allow for polyaxial rotation and sliding of the matched PEEK load bearing members relative to each other so that there are multiple PEEK outer bearing interfaces and a PEEK-on-PEEK inner bearing interface with the PEEK outer surfaces of the load bearing members forming the multiple PEEK outer bearing interfaces and the PEEK inner surfaces of the load bearing members forming the PEEK-on-PEEK inner bearing interface to allow for differential shifting of the different PEEK bearing interfaces optimizing wear resistance thereof and cyclical load capacity provided thereby.

43. (Canceled)

44. (Currently amended) The nucleus implant device of claim 42 wherein the arcuate inner bearing surfaces comprise ~~[[a]]~~ the dome-shaped inner bearing surface and ~~[[a]]~~ the corresponding arcuate recess-shaped inner bearing ~~concave-recessed~~ surface for receiving the dome-shaped inner bearing surface in engagement therewith with each engaging inner bearing surface being uninterrupted the entire extent thereof for smooth, continuous bearing engagement therebetween.

45. (Previously presented) The nucleus implant device of claim 42 wherein at least one of the load bearing members has a post configured to be engaged by a tool for implanting at least the one load bearing member in the intervertebral space.

46. (Currently amended) The nucleus implant device of claim 45 wherein both load bearing members include posts for a tool, and the arcuate inner bearing surfaces comprise ~~[[a]]~~ the

dome-shaped inner bearing surface and [[a]] the corresponding arcuate recess-shaped inner bearing ~~concave-recessed~~ surface sized such that with the dome-shaped inner bearing surface engaged in the corresponding arcuate recess-shaped inner bearing ~~concave-recessed~~ surface, the posts aligned with each other, and plate bodies of the load bearing members generally extending in parallel to each other, a predetermined gap spacing is provided between free ends of the aligned posts to avoid significant interference with the relative movement between the load bearing members at the inner bearing interface.

47. (Previously presented) The nucleus implant device of claim 42 wherein the load bearing members each have an elongated configuration with opposite narrow ends and long sides extending between the narrow ends allowing an incision in the annulus to be kept to a minimum size with the load bearing members inserted therethrough with the narrow ends leading the members through the incision.

48. (Previously presented) The nucleus implant device of claim 42 wherein the load bearing members include bodies that are entirely of the PEEK material including the bearing surfaces thereof less any radio opaque markers included in the PEEK bodies.

49-51. (Canceled)

52. (Previously presented) The device of claim 1, wherein the outer bearing surfaces are substantially race-track shaped for allowing the bearing members to fit within the natural annulus.

53. (Previously presented) The device of claim 1, wherein the narrow ends of the shells each have an arcuate configuration and the elongate sides extend parallel to one another between the narrow ends.

54. (Previously presented) The device of claim 1, wherein the smooth outer surfaces of the shells are entirely free of bone-engaging protrusions or surface roughening to promote sliding engagement of the bearing members with the end plates such that the nucleus device is allowed to move freely along the endplates within the annulus.

55. (New) The device of claim 1, wherein the truncated, diametrically opposite edge portions of the dome-shaped inner bearing surface extend substantially parallel to a longitudinal axis of the one shell body.